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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/094,921	06/15/1998	HORST LINDHOFER	80309	9008

7590

12/30/2004

M HENRY HEINES
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO, CA 941113834

EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/094,921

Applicant(s)

LINDHOFFER ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,13-21,23,26 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,13-21,23,26 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed on August 30, 2004 is acknowledged. Claims 31-35 are added.
2. Claims 1-8, 13-21, 23, 26 and 31-35 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

4. The rejection of claims 23 and 26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.
5. The rejection of claims 23 and 26 under 35 U.S.C. 102(b) as being anticipated by Hanna, Jr. (U.S. Patent 5,484,596; issued Jan. 16, 1996) is withdrawn in view of the amendment to claims 23 and 26.
6. The rejection of claims 23 and 26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,551,592 in view of Volker (U.S. Patent 5,911,987) is withdrawn because the inventions of claims 1-13 of U.S. Patent No. 6,551,592 are limited to methods consisting of administering to the subject intact

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heterologous bispecific antibodies. Therefore, the methods of claims 1-13 of U.S. Patent No. 6,551,592 are outside the scope of the methods of claims 23 and 26 of the instant application.

Rejections Maintained:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-8, 13-21, 23 and 26 are directed to an invention not patentably distinct from claims 1, 7, 10, 19, 22 and 23 of commonly assigned U.S. Application 10/378,218. Specifically, the methods of claims 1, 7, 10, 19, 22 and 23 encompass the claimed methods and make obvious the pharmaceutical composition of claim 26.

Claims 1-8, 13-21, 23 and 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 10, 19, 22 and 23 of copending Application No. 10/378,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions of copending application No. 10/378,218 encompass the claimed methods and pharmaceutical compositions of claims 1-8, 13-21, 23 and 26 of the instant application. While the claims of

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10/378,218 are broader in scope than claims 1-8, 13-21, 23 and 26 of the instant application, the specification of 10/378,218 teaches heterologous bispecific antibodies of the same scope as recited in claims 1-8, 13-21, 23 and 26 as a preferred embodiment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants' remarks concerning the withdrawal of this rejection if the provisional double-patenting rejection is the only remaining rejection in the application are noted.

New Grounds of Rejection:

8. Claims 14, 23, and 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite because the phrase "said intact heterologous bispecific antibodies" lacks antecedent basis. In claim 14, step (c) of claim 1 is replaced by step (d), and it is in step (c) that bispecific antibodies are set forth.

Claim 23 is indefinite because the phrase "such tumor cells" lacks antecedent basis. This rejection would be obviated if claim 23 were amended to recite : "...in whom tumor cells have reappeared...".

Claim 32 is indefinite because the phrase "said intact heterologous bispecific antibodies" lacks antecedent basis. In claim 32, step (c) of claim 1 is replaced by step (d), and it is in step (c) that bispecific antibodies are set forth.

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Claim 32 is indefinite because the phrase “such tumor cells” lacks antecedent basis. This rejection would be obviated if claim 32 were amended to recite :”...in whom tumor cells have reappeared...”.

Claim 35 is indefinite because it appears to be of the same scope as claim 31.

9. Claims 31 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Honsik (U.S. Patent No. 4,844,893; issued July 4, 1989; cited in previous Office actions).

Because claims 14 and 32, from which claims 31 and 35 depend, are indefinite with respect to which bispecific antibodies are used to make the pharmaceutical compositions, the claimed pharmaceutical compositions appear to contain within their scope compositions of activated peripheral blood mononucleated cells that were made using any type of bispecific antibody. Furthermore, claims 31 and 35 are product by process claims that are drawn to compositions comprising “activated peripheral blood mononucleated cells”. It is not clear from the specification that the cells resulting from the methods of claim 14 or claim 32 are materially different from “activated peripheral blood mononuclear cells” obtained by any other method.

Honsik teaches methods of activating peripheral blood mononuclear cells comprising mixing mononuclear cells with bispecific antibodies and tumor cells (see column 4, line 55 – column 5, line 55). Therefore, Honsik teaches compositions of activated peripheral blood mononuclear cells that are same as that claimed.

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10. Claims 31 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Renner (Renner, C., et al, Science 264: 833-835, 1994).

Claims 31 and 35 are product by process claims are drawn to compositions comprising "activated peripheral blood mononucleated cells". It is not clear from the specification that the cells resulting from the methods of claim 14 or claim 32 are materially different from "activated peripheral blood mononuclear cells" obtained by any other method.

Renner teaches activated peripheral blood mononuclear cells (page 833, 3rd column to page 834, 1st column, and Table 1). Therefore, Renner teaches compositions that are the same as that claimed.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
December 27, 2004


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
12/29/2004